

EXHIBIT 73

From: Paul Galea <pgalea@actavis.com>
Sent: Monday, February 2, 2009 3:54 PM
To: Tony Delicato <TDelicato@actavis.com>
Subject: QRB minutes
Attach: QSD-141_QRB minutes_01_09.pdf

Hi Tony,

Please find attached.

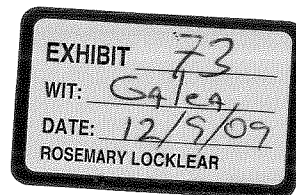


Paul Galea
QA Director, Documentation
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NJ 07424 Little Falls USA f mp_ofax w mp_oWeb

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PLAINTIFFS' EXHIBITS 000102





Quality Review Board

Meeting date: January 26, 2009.

Attended: Tony Delicato, Misbah Sherwani, Elisabeth Guarch, Brian Nizio, Dorota Sobczyk, Jason Ellis, Ashesh Dave, Mike Puorro, Michael Redmond and Marjorie Demko

Absent: Jacob Haroon, Annie Cheung and Vince Warren

Meeting chaired by: Paul Galea

Meeting Minutes:

All provided metrics were reviewed during the meeting. There were no metrics which were indicative of negative trends. Refer to Annex I for QRB presentation.

No QC metrics were provided for this meeting.

Training:

Out of 26 departments 14 are less than the target of 90%. Of these 38% are less than 85% trained. The site training percentage has risen to 75% from 74% in December 2008. This is still low compared to the target of 90%

Recall: no metrics available.

Expired SOPs:

In all five SOPs are still expired. These will be addressed by the owners by the next QRB meeting.

Change Control:

Target date for implementation of Trackwise was confirmed for January 30. No new change controls will be issued in the paper system after this date. Existing change controls will be closed as per system they were initiated in.

Annual Product Reviews:

All APRs issued on target. Positive trend maintained for four months.

CAPA:

All 2008 CAPAs have extension reports in place. QC CAPAs to be verified for the exact number still open.



Quality Review Board

Investigations:

The average cycle time for closure of lab related investigations went down to 17 days during the month of January. No investigations were open for more than 30 days. This trend has been steadily maintained for lab and non lab investigations since Jul 2008 (exception being for August where the non lab were at 31 days).

Complaints:

63 AE complaints were closed in January with an average cycle time of 70 days to close.

Facilities and Preventative Maintenance:

Percentage closed is 100% and on target.

Calibrations:

The decrease in total active records is because the decommissioned equipment is no longer being reported. Only 42% is given as completed on time, reason being that the month was not yet over.

Discussion:

During the meeting it was decided to obsolete SOP 0063 Qualification of Production Areas. This will be assigned as an action item to Technical Services.

The action item to indicate the training status for Managers is still open. Action assigned to training Department.

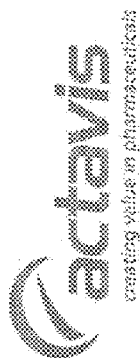
The action item for the setup of a separate CAPA meeting is still open. Action assigned to QAIG.

QSIP metrics shall be included in QRB as from next meeting.

QRB meeting for February shall be held in the first week of March in order to have metrics for the full month. This will be done for all upcoming meetings going forward.

Paul Galea
Director, Documentation
February 2, 2009.

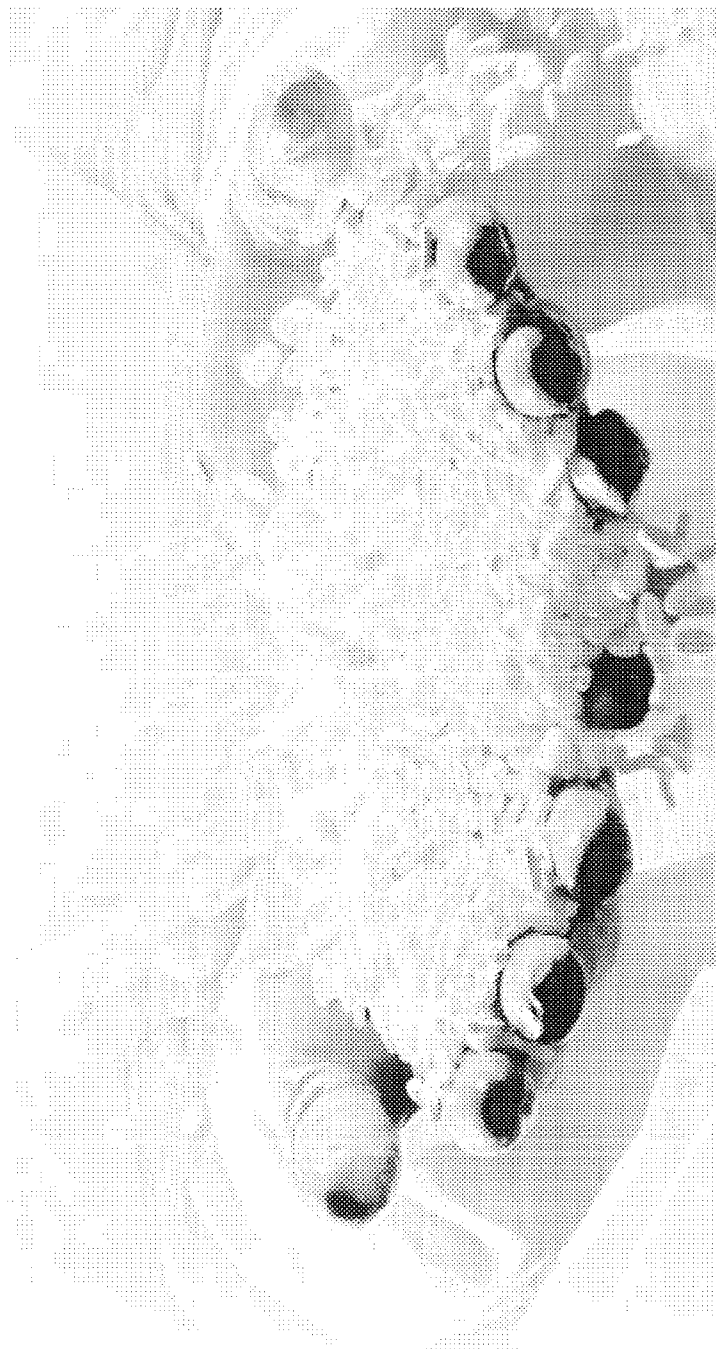
APPENDIX I



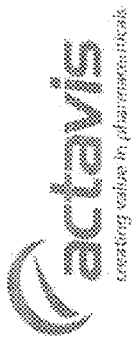
Quality Review Board

Actavis Totowa LLC

Meeting # 5 - January 26, 2009



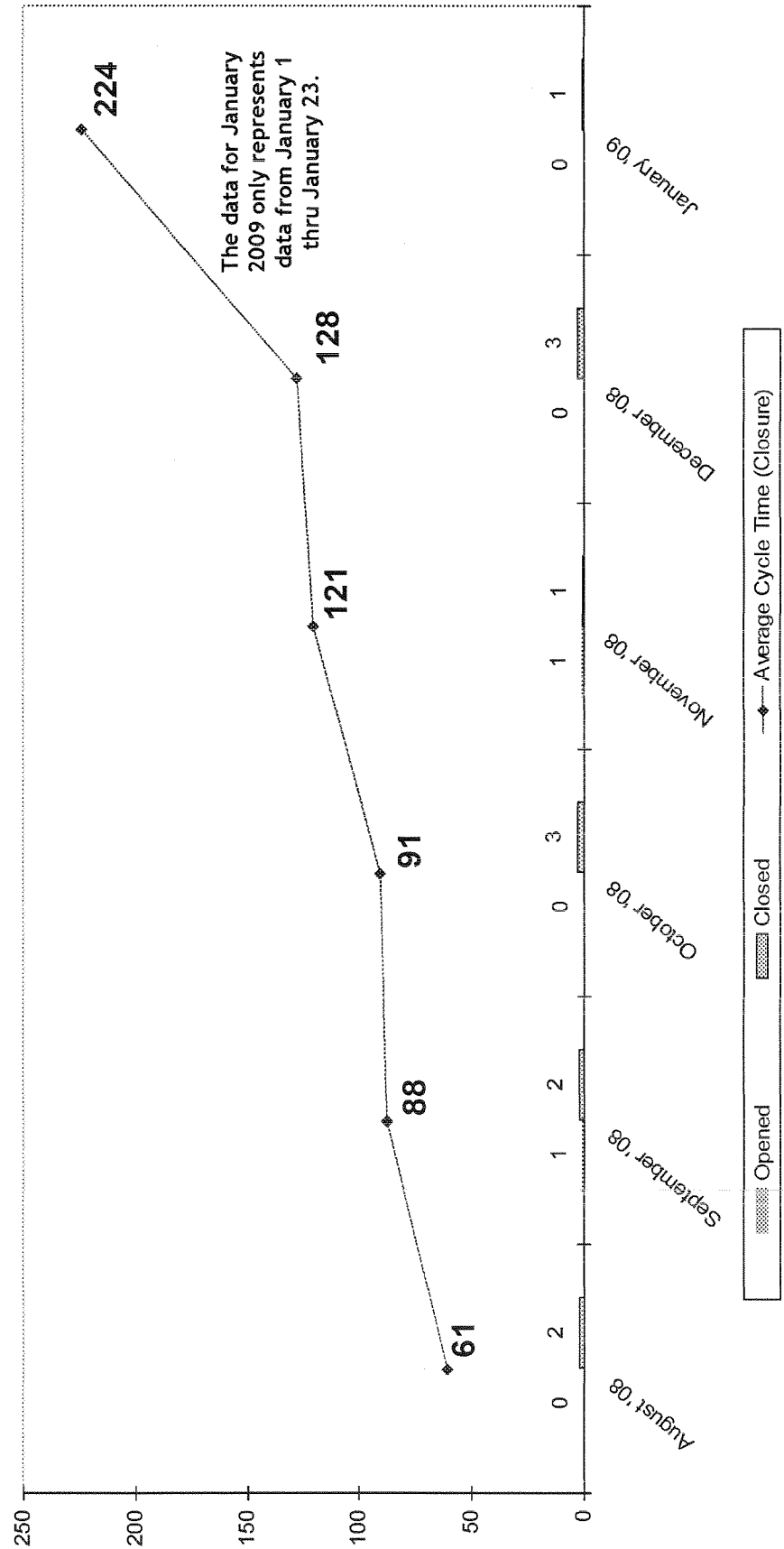
PLAINTIFFS' EXHIBITS 000106



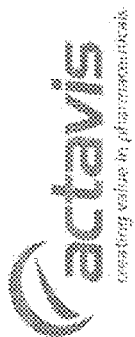
Quality Review Board

January 2009

Little Falls Product Complaints



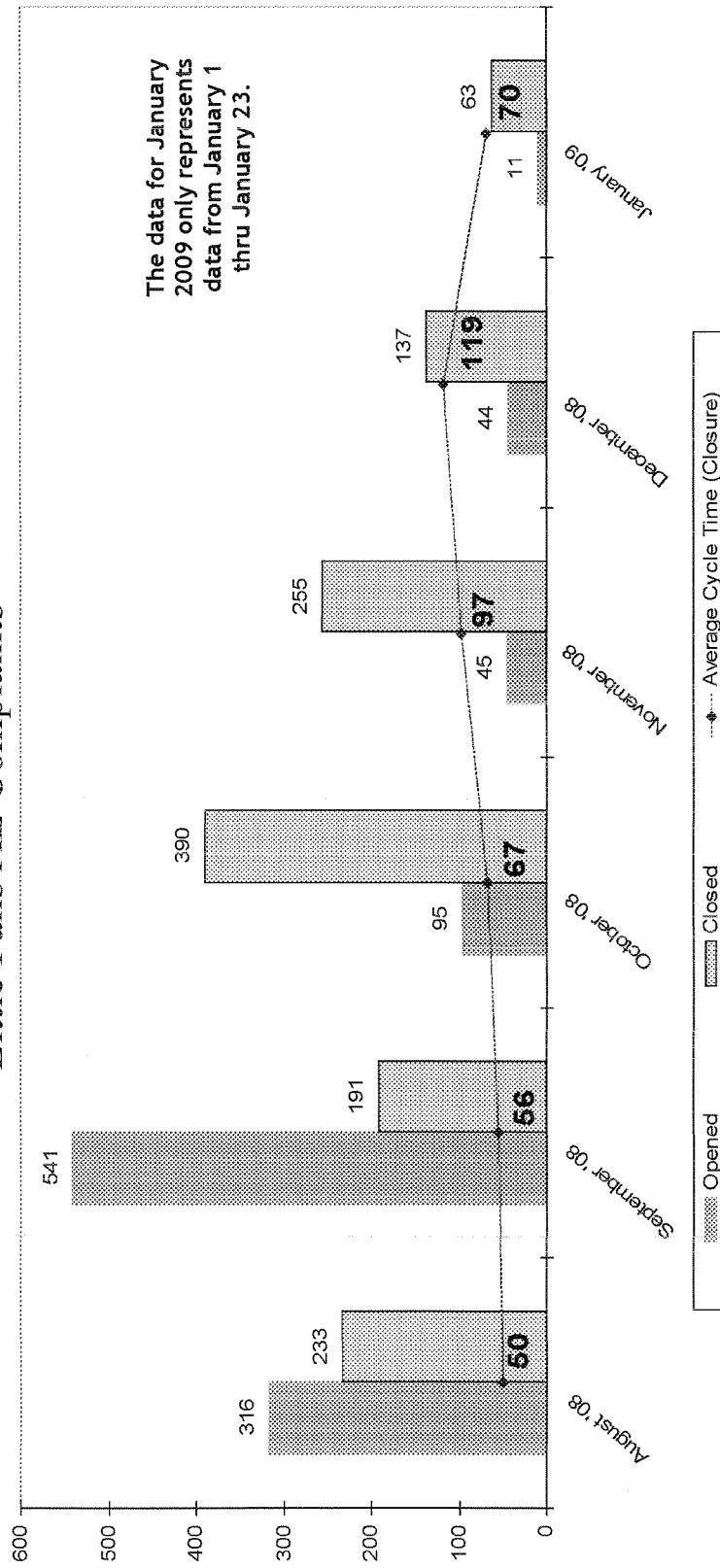
PLAINTIFFS' EXHIBITS 000107

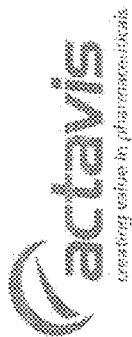


Quality Review Board

January 2009

Little Falls AE Complaints

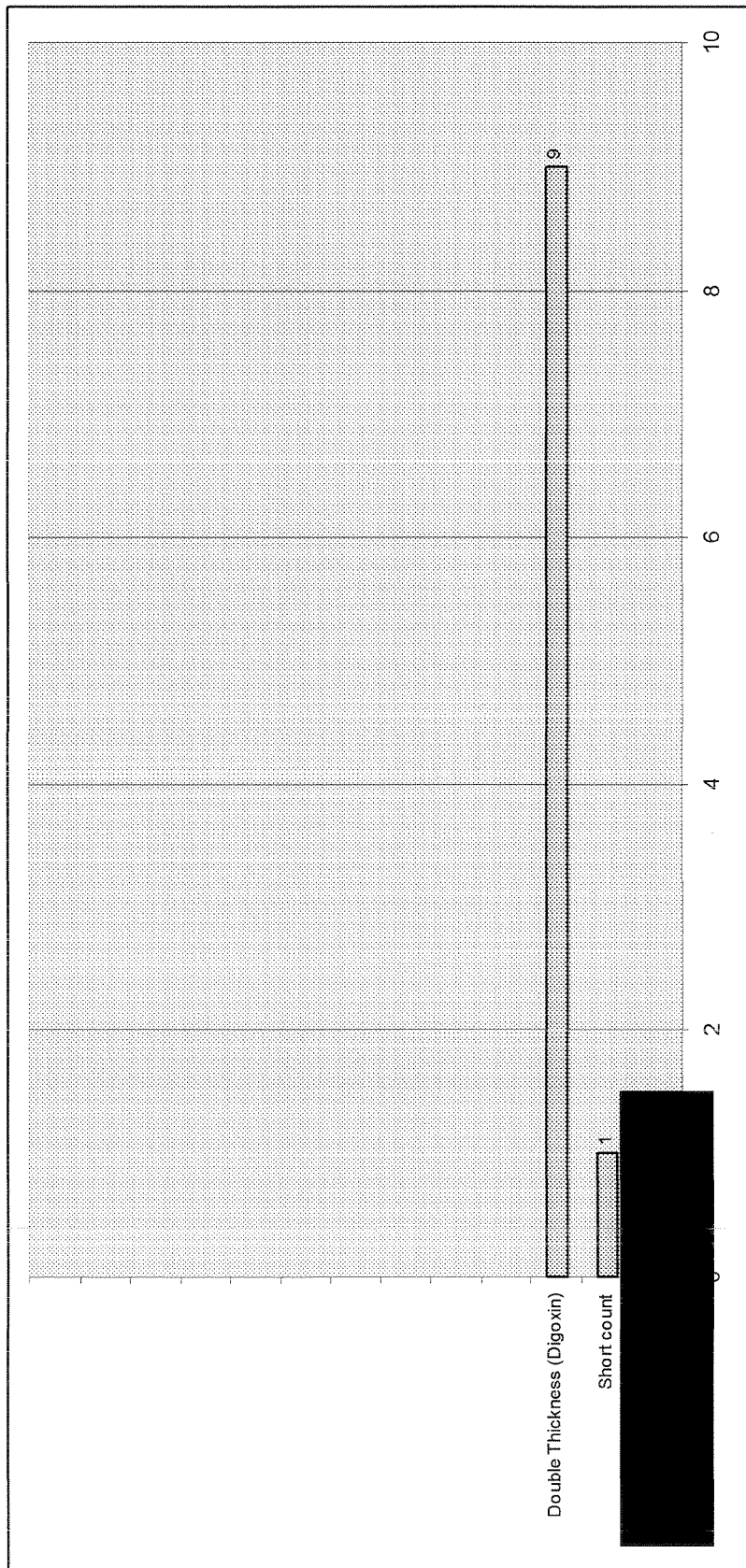


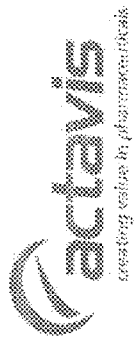


Quality Review Board

January 2009

Little Falls Product Complaints by Category (August 2008 to January 2009)



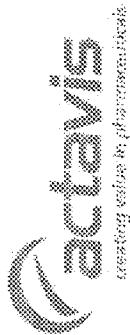


Deviations and CAPA Partial Data (ending 1/23/09)

PREVENTIVE ACTIONS - Little Falls as of 1/23/09

	Remaining from 2008 Manual System	DEC 2008 TW system	JAN 2009 TW
Initiated	N/A	12	8
Total Open	47	9	4
# Overdue	24	0	0
% Overdue	51%	0%	0%
CAPA Completed	N/A	3	4
# CAPA Completed On time	N/A	1	4
% CAPA Completed On Time	N/A	33%	100%

Data does not include Corrective Actions (immediate actions); only PAs Preventive Actions



Monthly Report

January 2009

Overview of Open CAPAs by Department (Preventive Actions only) as of 1/23/09

Department	# of PAs manual system	# of PAs TW system	# overdue Manual system	# overdue TW
AR	7	1	4	0
ENG	8	3	3	0
MFG	6	1	6	0
PKG	1	0	1	0
QA	4	1	3	0
QC	14	4	6	0
RA	1	0	1	0
RD	2	0	0	0
Validation	4	3	0	0
Total	47	13	24	0
		% Overdue	51%	0%

Includes 2008 data in totals

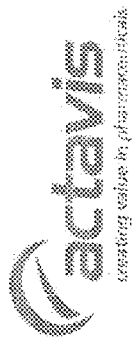


Monthly Report

January 2009

- Deviation Investigations: *Non-Laboratory vs Laboratory - Little Falls*

January 2009 As of 1/23/09	Totals	Non Laboratory	Laboratory
Total Initiated (20 total)	20	4	16
Total Closed (w/in Month)	2	0	2
Total Open (at month end) YTD	18	4	14
Total Open > 30 days	0	0	0
Oldest Open (days)	N/A	N/A	N/A



Monthly Report

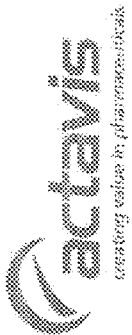
January 2009

Detailed Information for

Non-Lab Deviations vs Laboratory Deviations

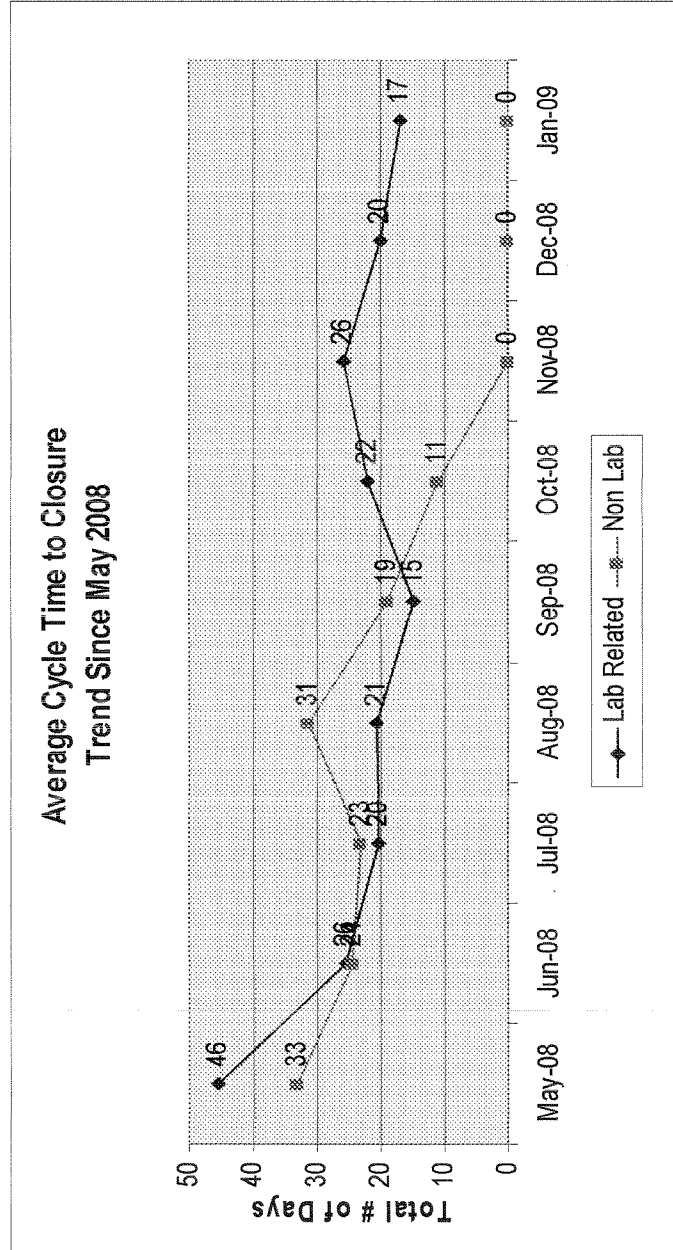
Exceeding 30 days

Inv #	Date Issued	Batch #	Product #	Product Name	Extension date	Days Open
Not applicable - no deviations over 30 days						



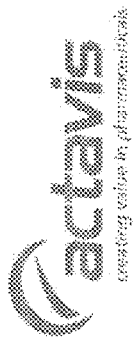
Monthly Report

January 2009



Cycle time based on closed Deviations only

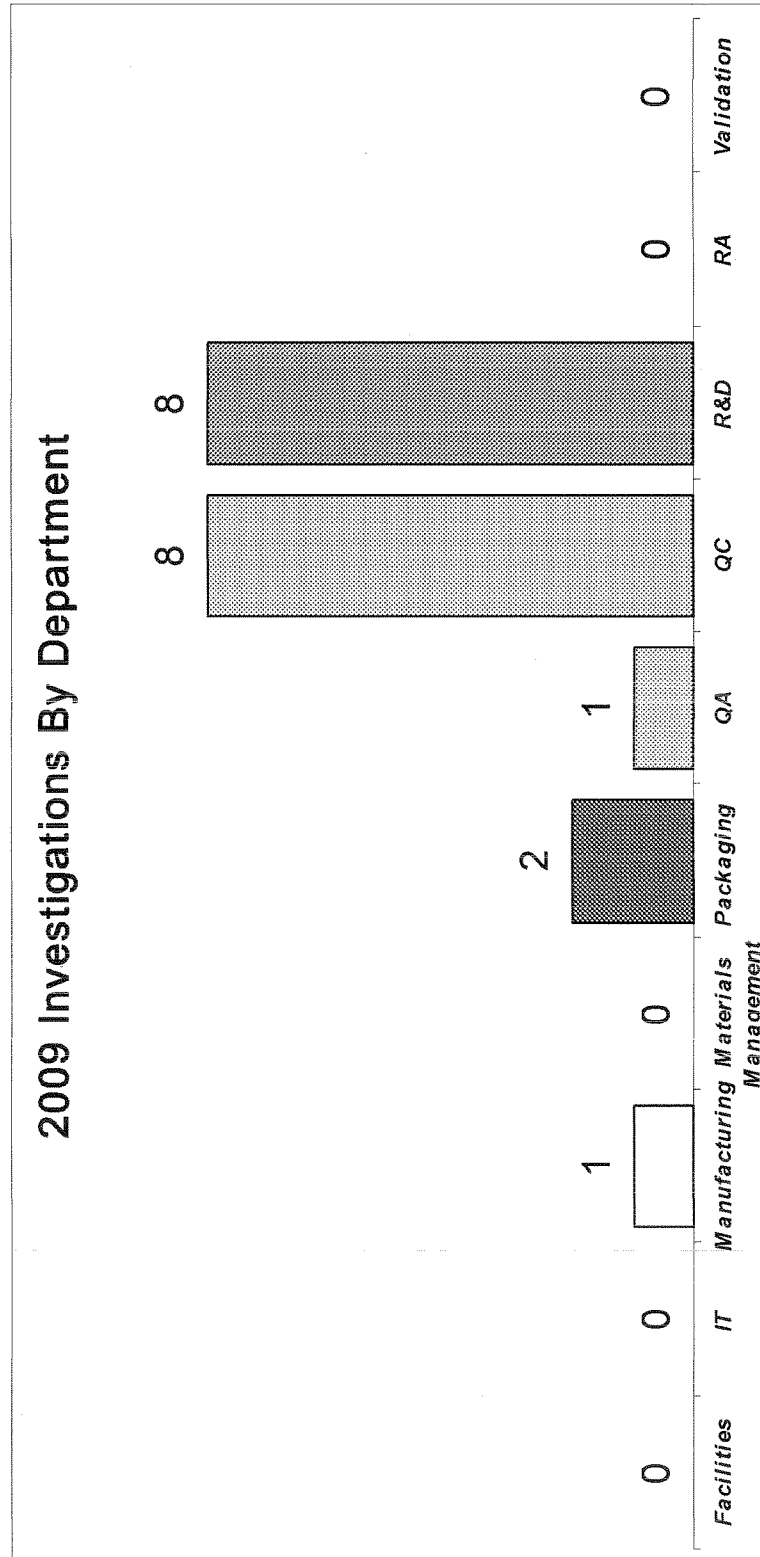
Zero (0) deviations for Non Lab Deviations indicates that none were closed during that reporting month

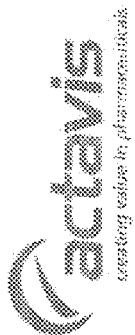


Monthly Report

January 2009

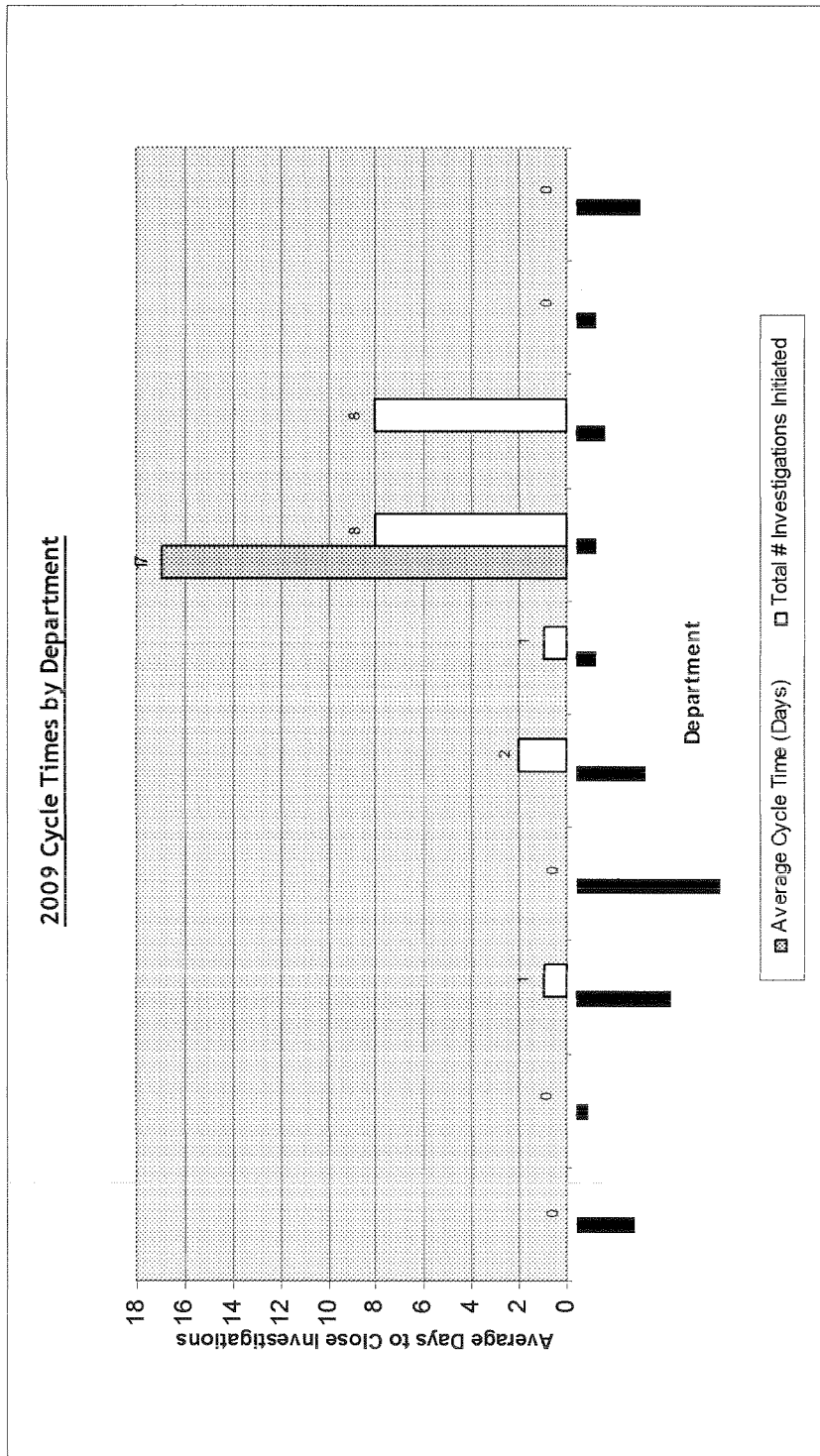
2009 Investigations By Department

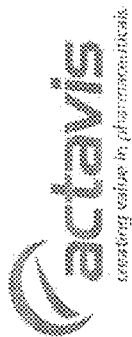




Monthly Report

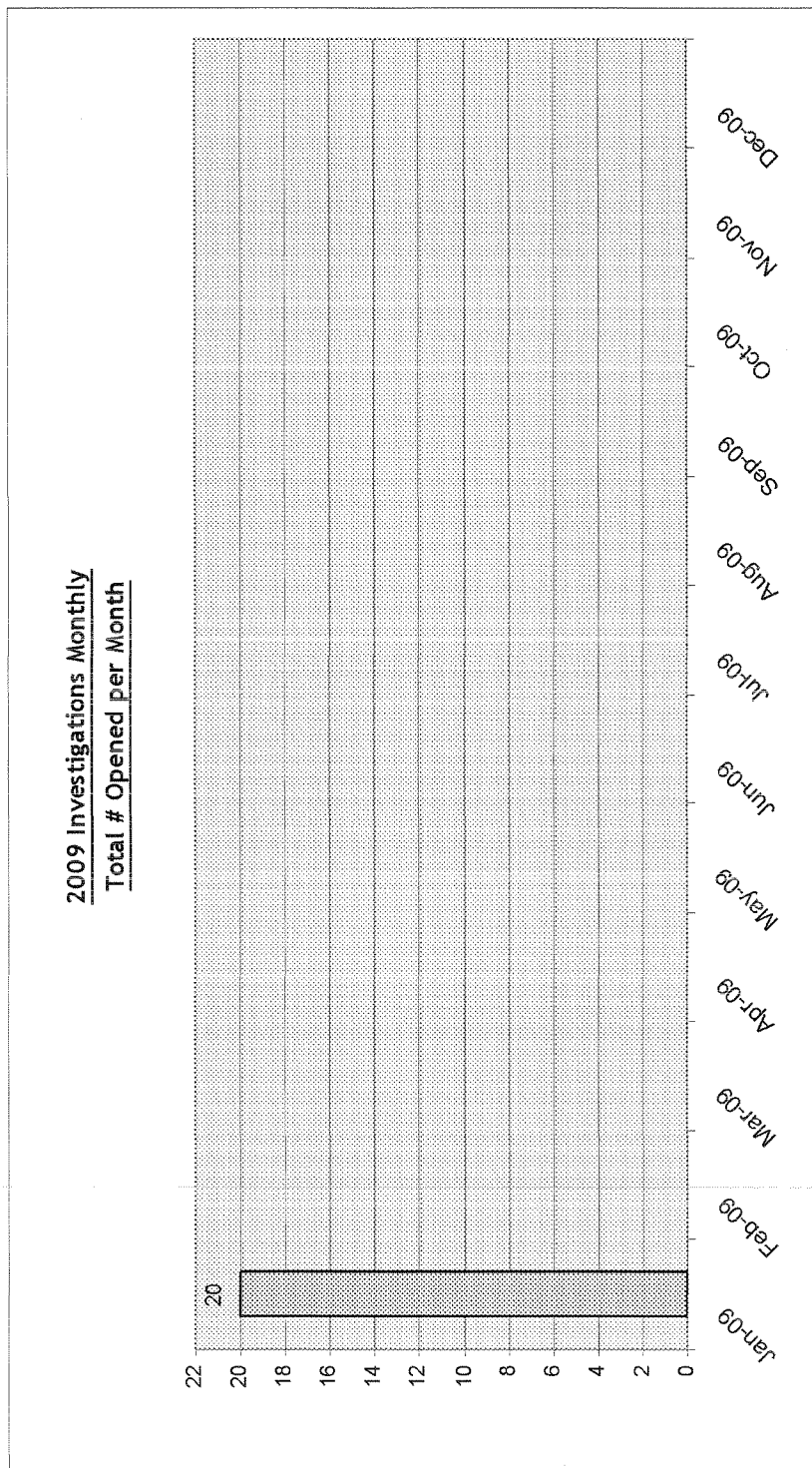
January 2009

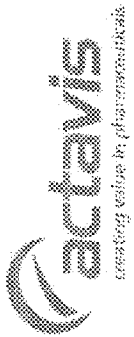




Monthly Report

January 2009

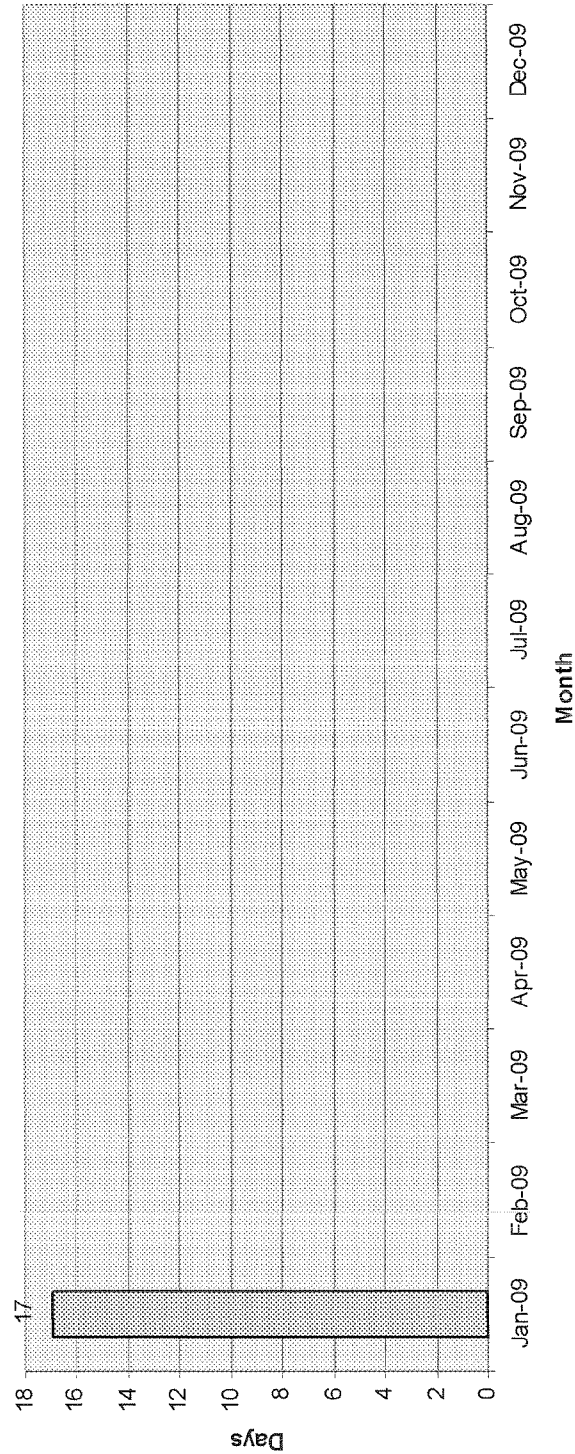




Monthly Report

January 2009

Average Monthly Cycle Time For Investigation Closure





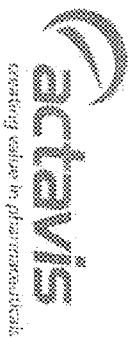
Training

Totowa Site Training Assessment

Month	% Completed Training for All Departments
October	56%
November	67%
December	74%
January '09	75%

Note: Data is impacted by changes to training requirements (syllabi), new employees and terminated employees.

The data reported reflects training records received/entered through January 22, 2009. Training records received after this date will be reported in the next report.



Training

Departments less than 90%

Department	%
Operations Admin	70%
Engineering Admin	65%
QA Investigations	84%
QA Documentation	87%
Site Training	86%
Regulatory Affairs *	38%
Research & Development	36%

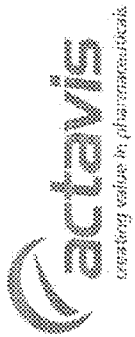
Department	%
Product Development	45%
Shipping & Receiving	48%
Purchasing	38%
Supply Chain	89%
Human Resources	70%
EHS	18%
Site Security *	37%

Total Departments = 26

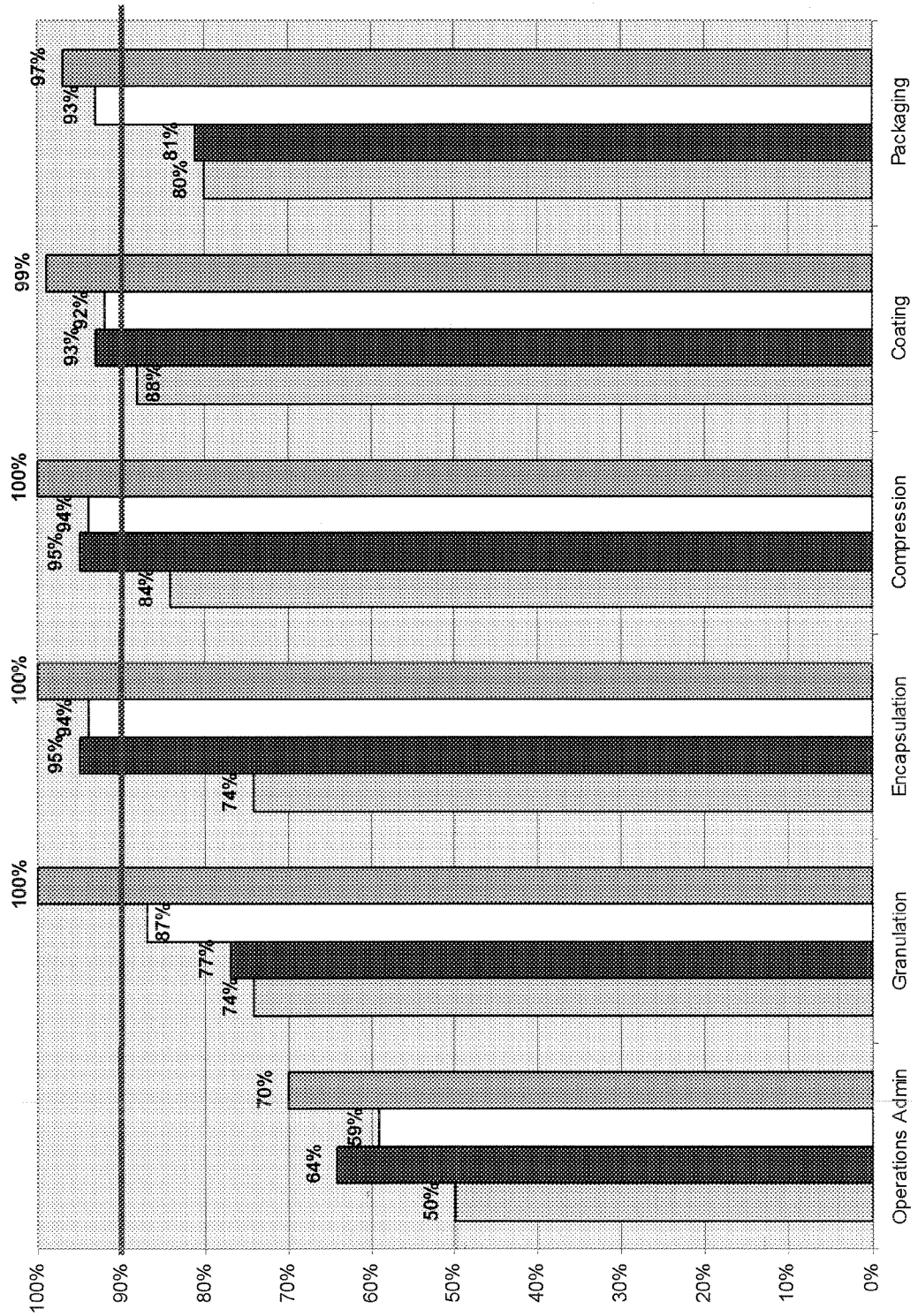
Total less than 90% =14

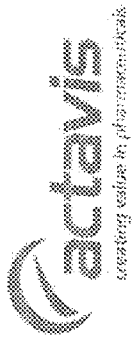
53% are less than 90%
38% are less than 85%

* Syllabi adjustment in progress

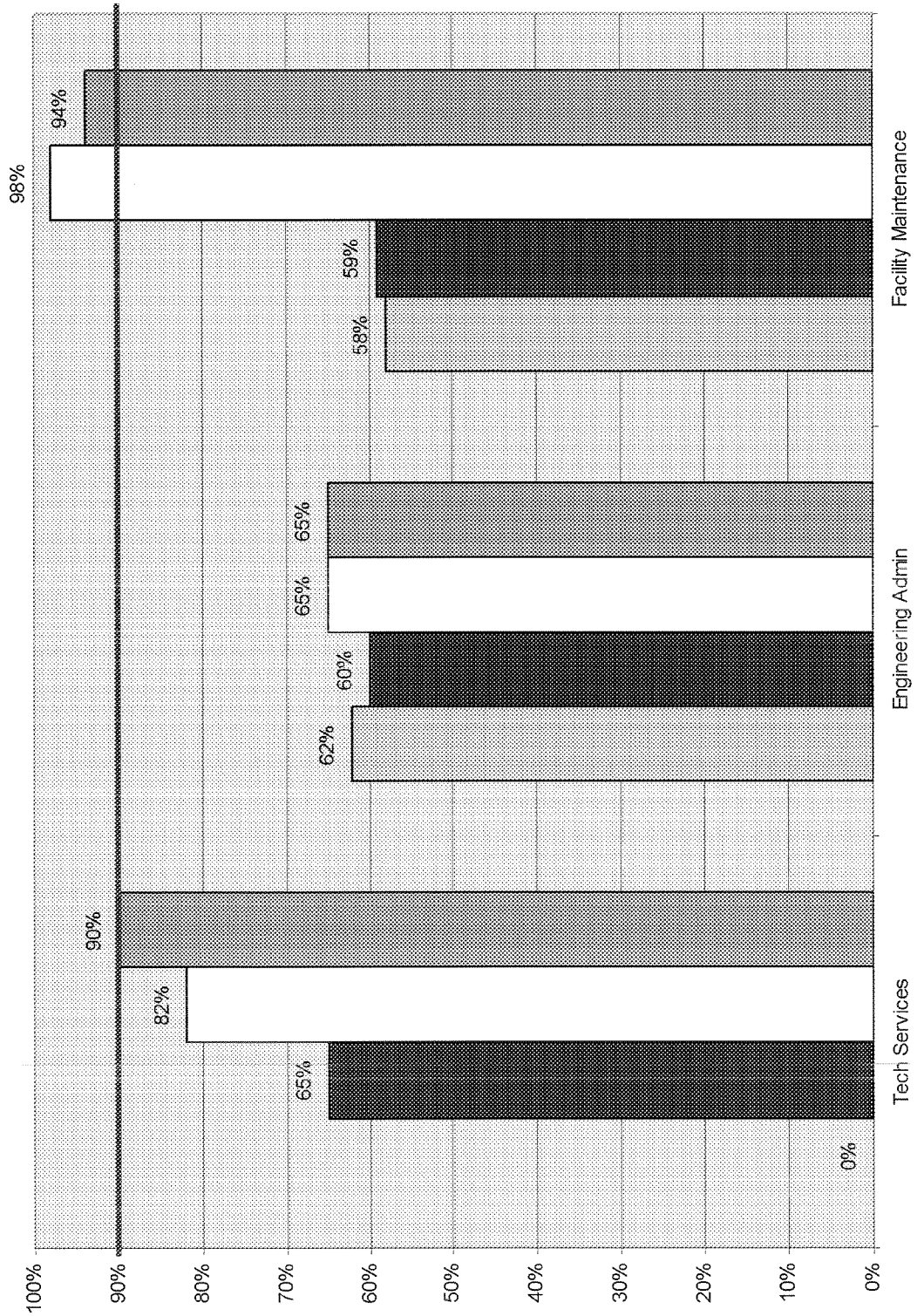


Training



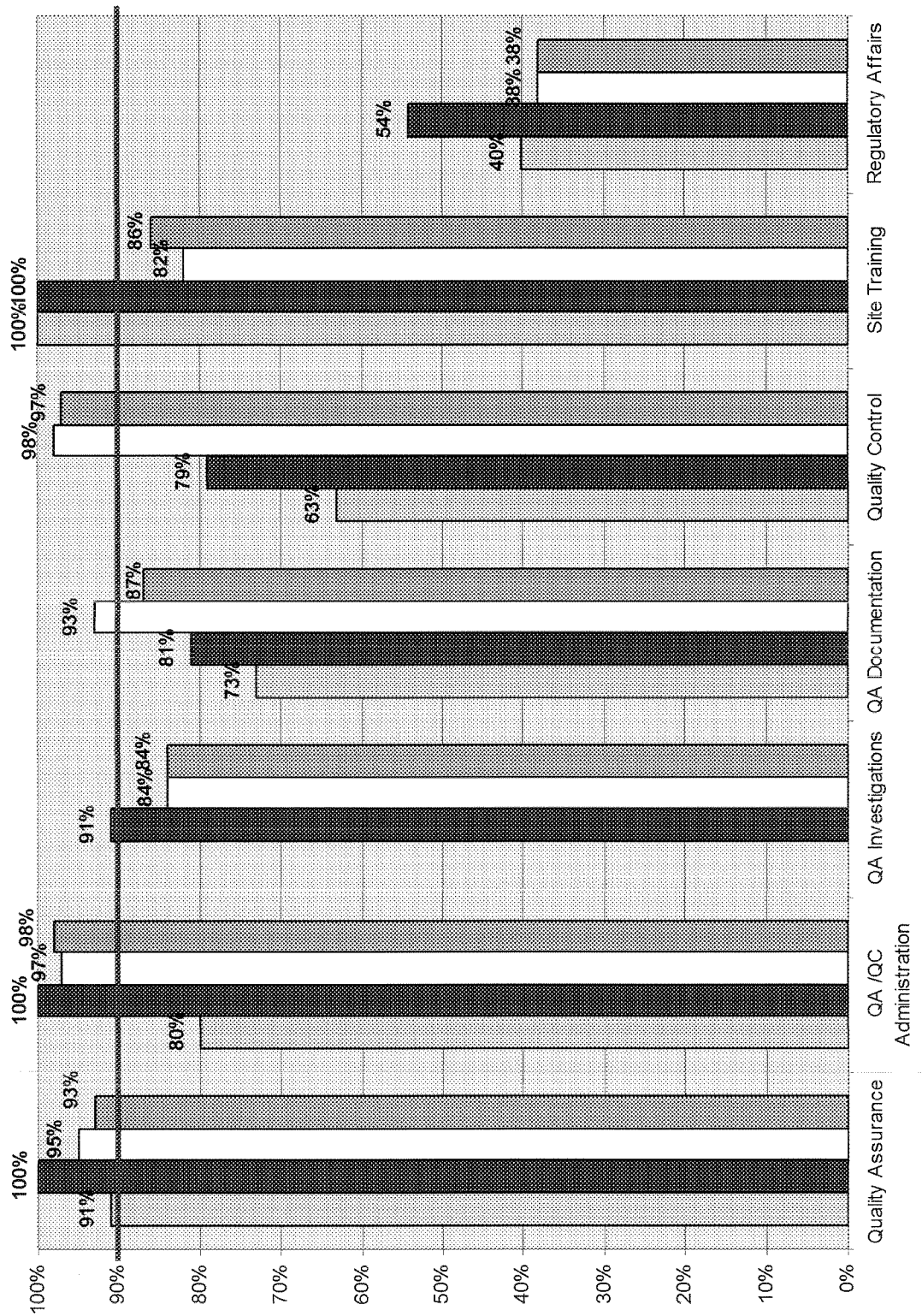


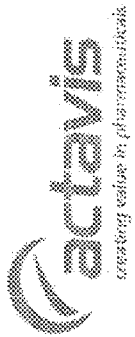
Training



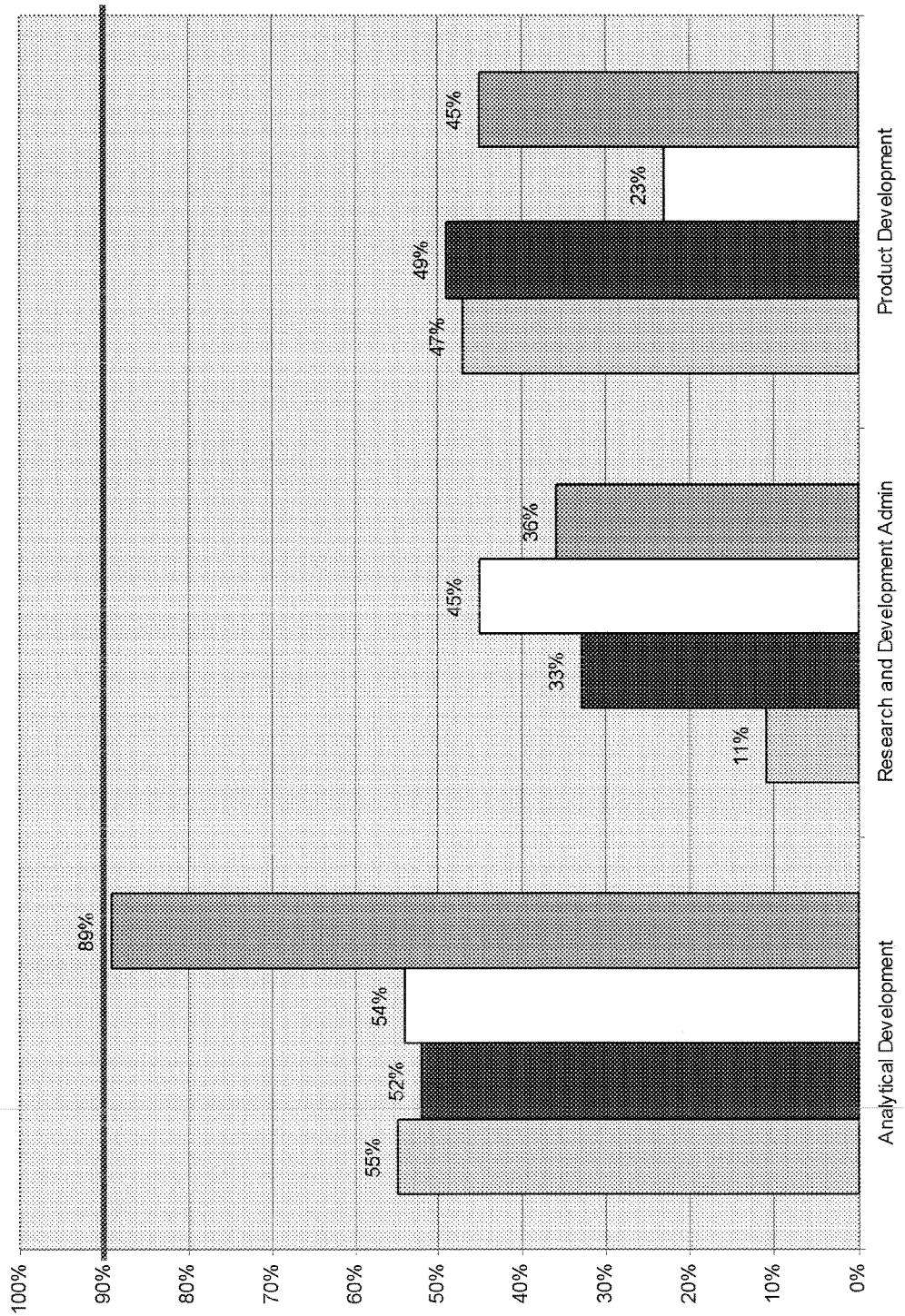


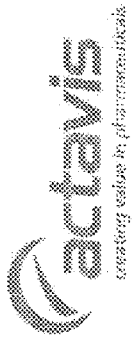
Training



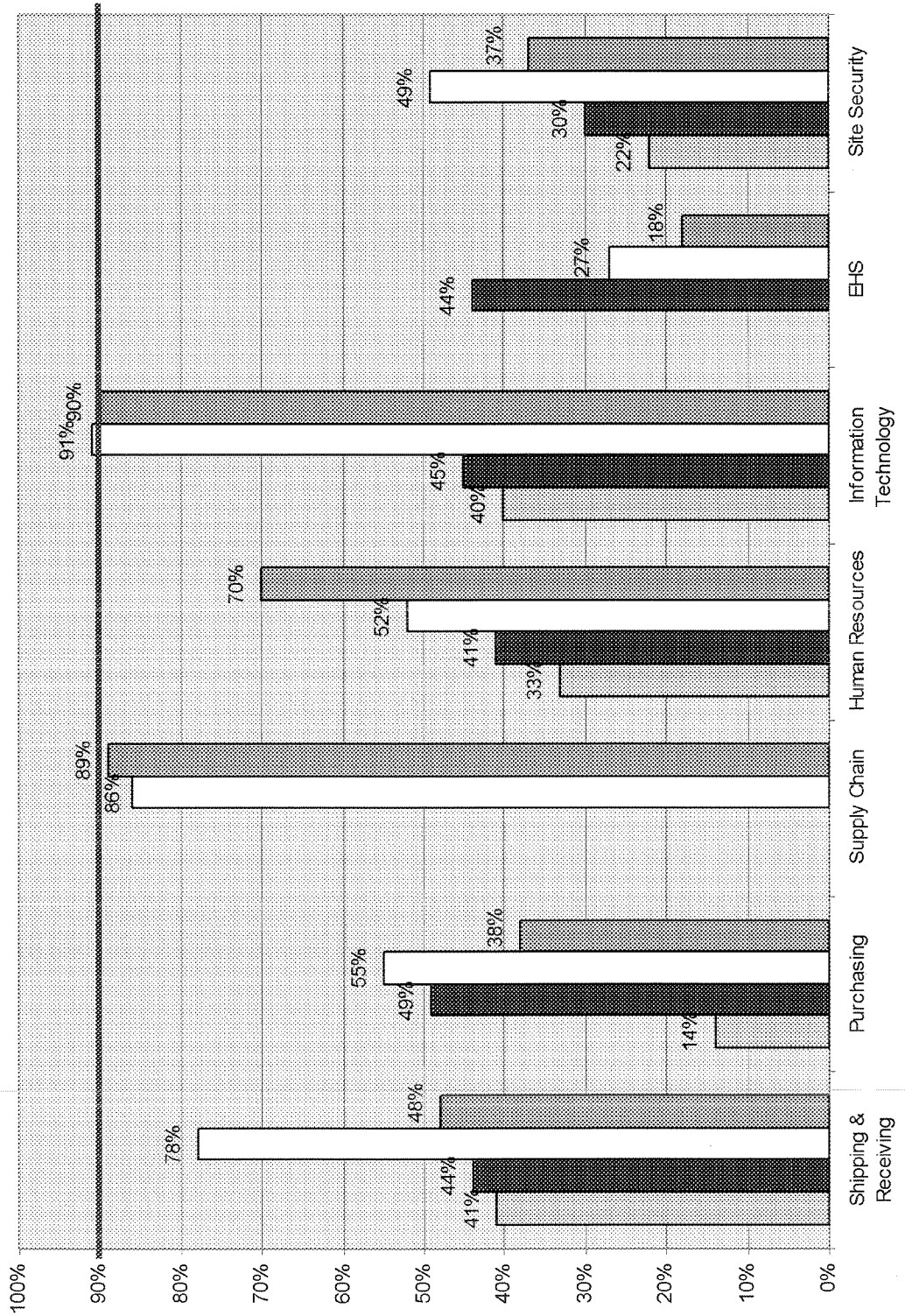


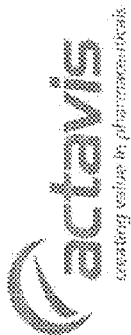
Training





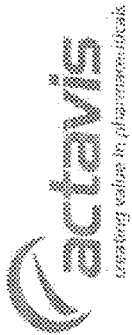
Training





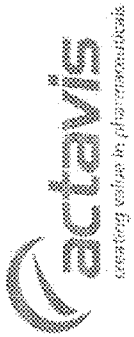
Training

- ❖ New QRB Requirement
 - All departments must target 90% for completed training
 - Site Training will provide the necessary information, work with each group and will follow-up to meet the goal.
- ❖ NEW CAP (Competency Assessment & Performance) - Training System
 - Online Training & Assessments (View your training gaps anytime)
 - Web-Based application (access from anywhere)
 - Learning Management System (LMS)
 - Web-Based application (access from anywhere)
 - Divisional Training Courses (All US sites)
 - GMP Training
 - Train-The Trainer
 - Corporate Training
 - Validation to begin - Q1 2009; Target to implement CAP - Apr. 09



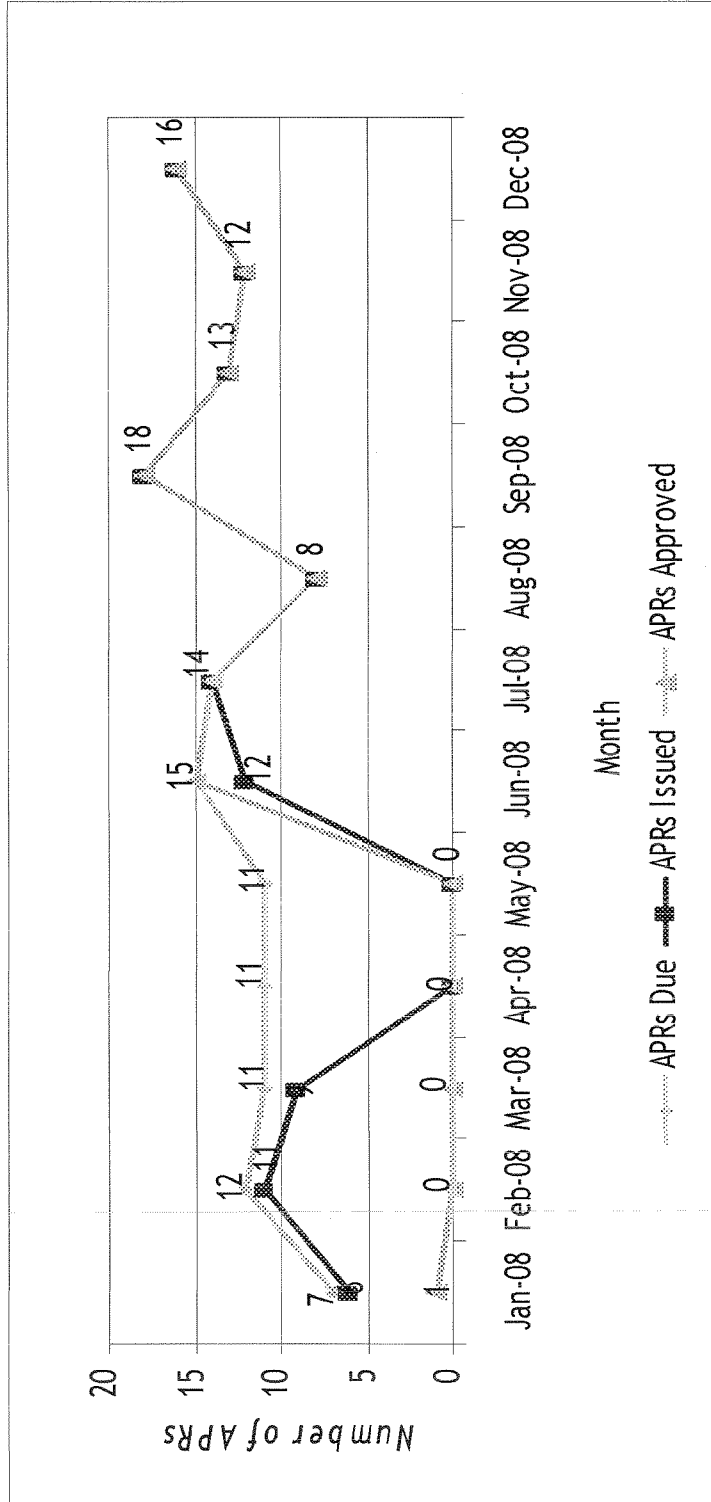
Training

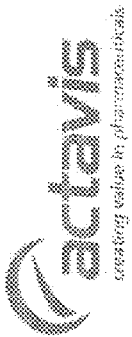
❖ Monthly Training Reports are targeted to be distributed to Training Contacts & Department Management within the 1st week of each month



APRs

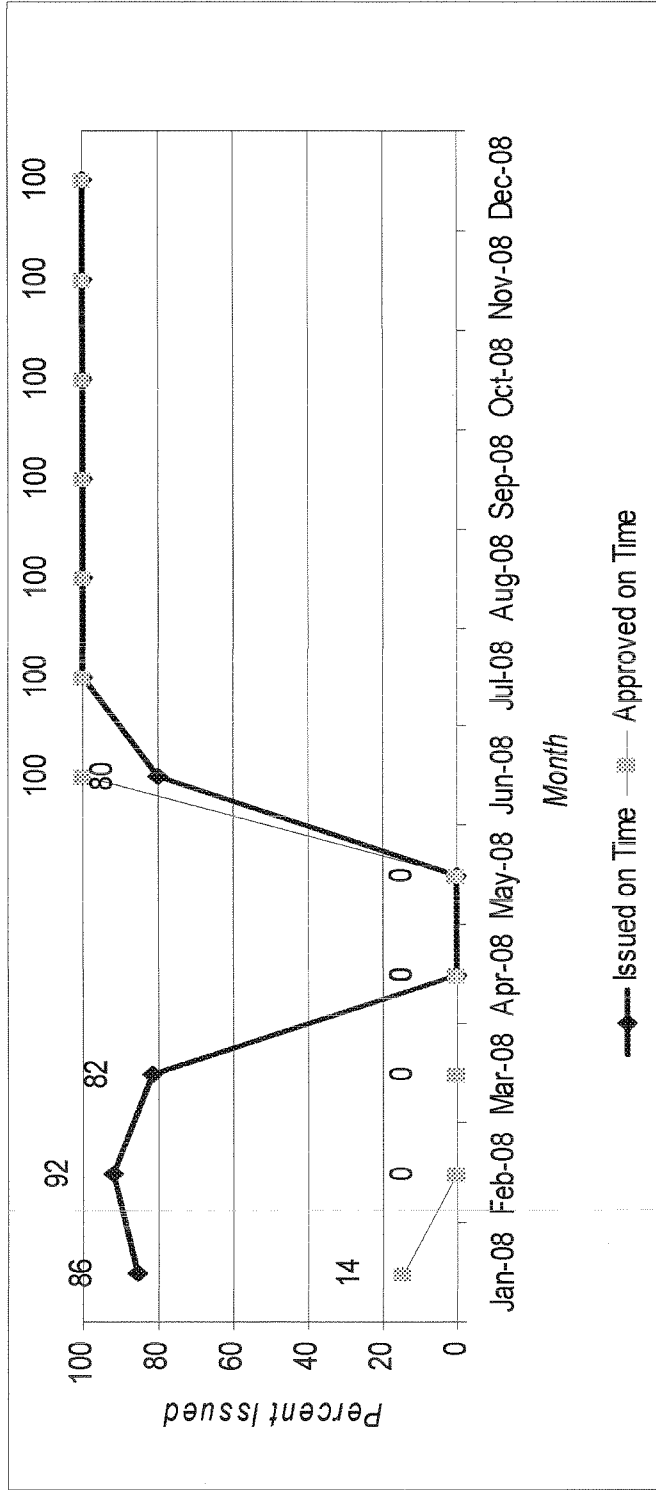
Figure 1 Number of APRs Due, Issued, and Approved (Monthly Basis)

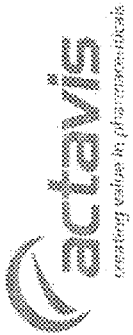




APRs

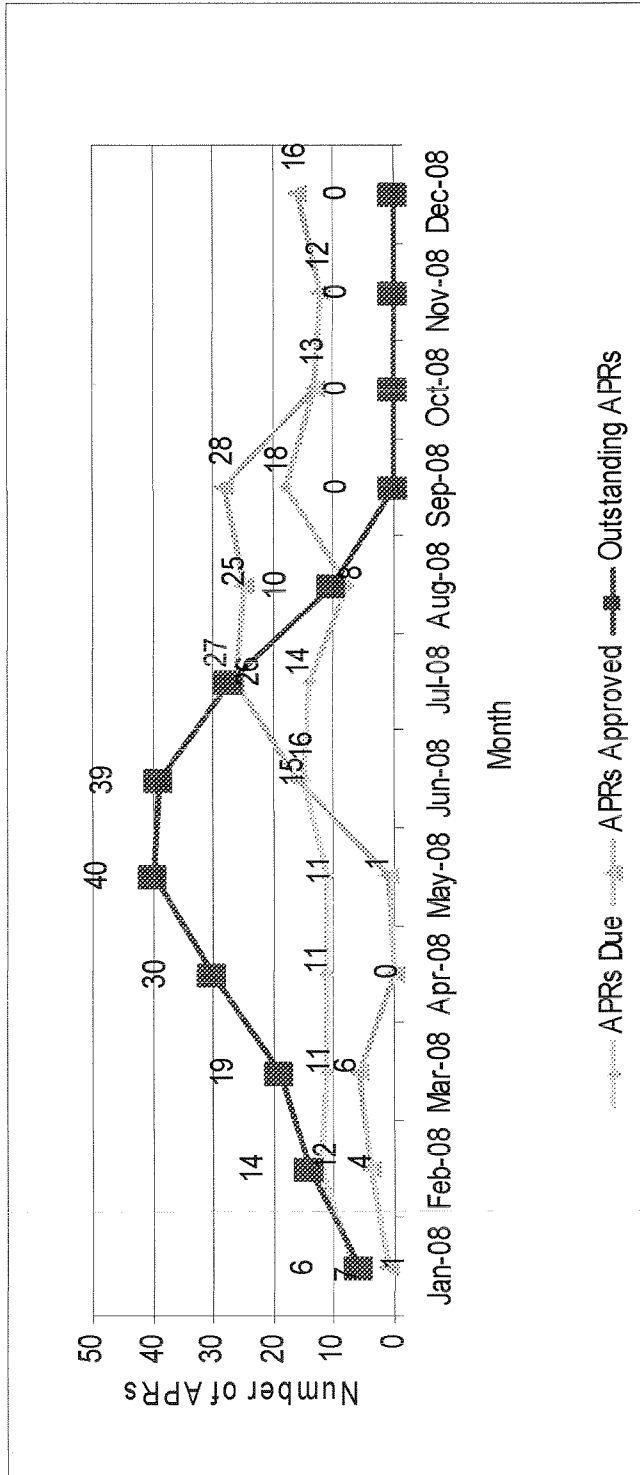
• Figure 2 Percentage of APRs Issued and Approved on Time (Monthly Basis)

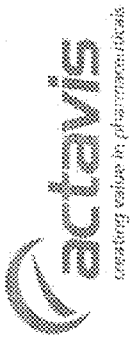




APRs

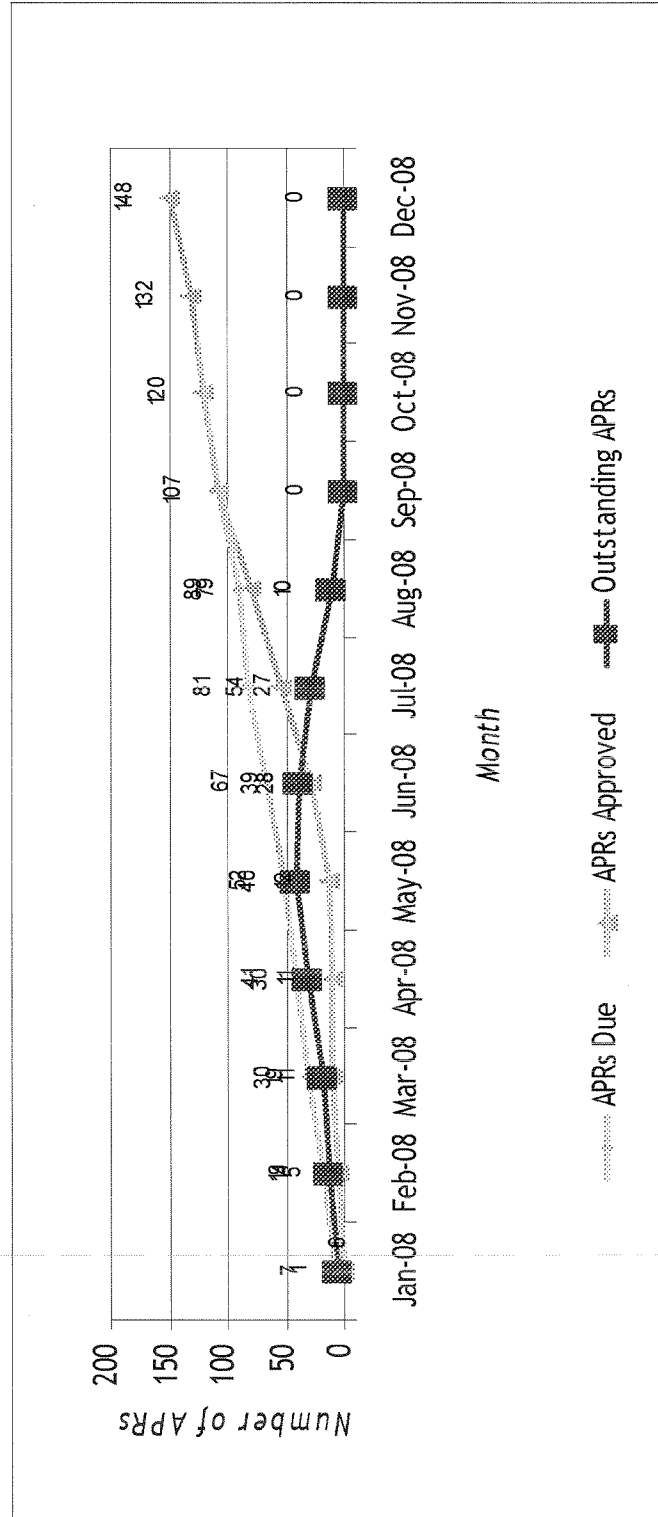
• Figure 3 Number of APRs Due, Outstanding, and Approved (Monthly Basis)

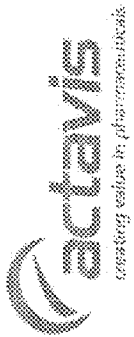




APRs

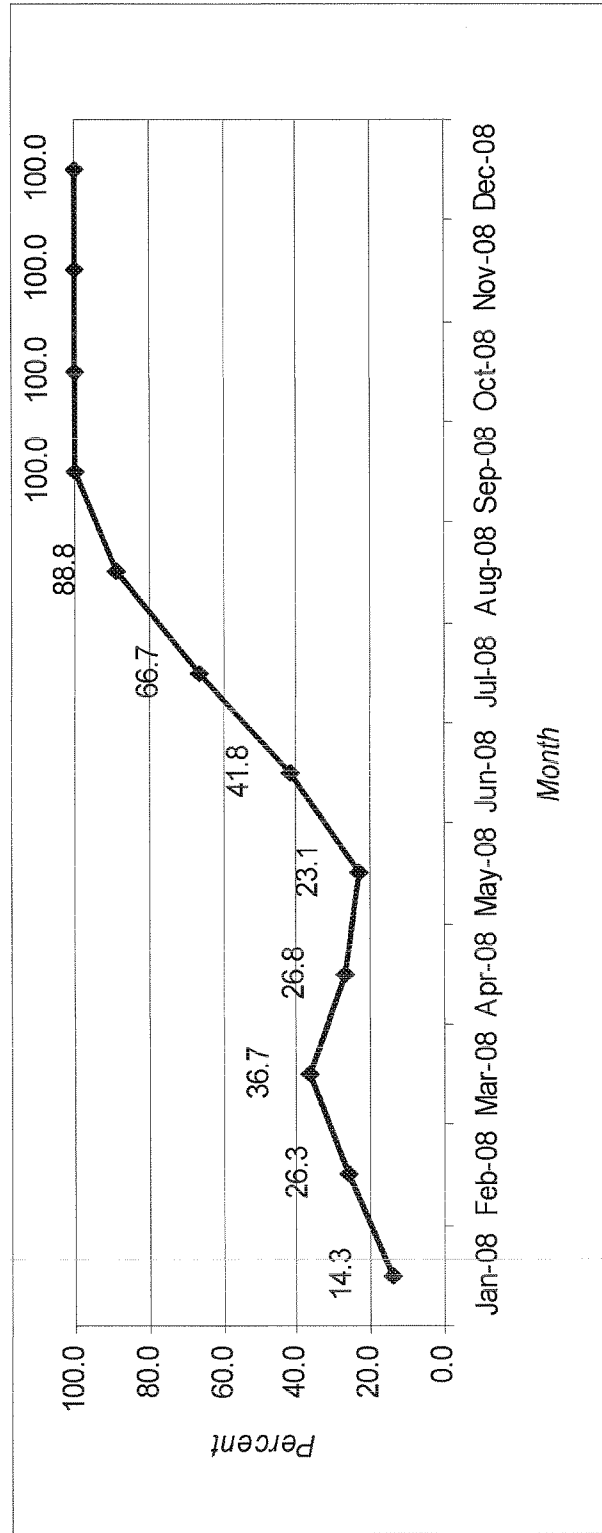
• Figure 4
Date Number of APRs Due and Approved Year-to-

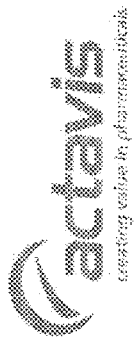




APRs

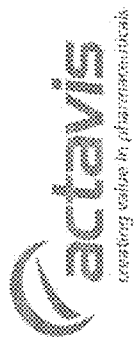
• Figure 5 Percentage of APRs Approved Year-to-Date





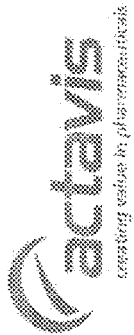
Expired SOPs

SOPs Expired			
SOP_No	Iss	SOP_Title	Implemen
0063	02	Qualification of Production Areas	03-Jan-06
0067	00	Technology/Product Transfer	01-May-00
0068	01	Setting Specifications	07-Nov-05
0029	00	R & D Batch Conversion	19-Aug-92
0032	04	Control of Contract Processing Operations	07-Nov-05



Change Control

• Issued:	32
• Approved:	11
• Rejected:	1
• Open >90 days:	12



Change Control

CHANGE CONTROL FLOW WORKSHEET 2008

CC #	Doc #	Type	Content Ref#	Doc Name	Date Initialed	Owner	Department	TO BE CHANGED	Date Sent	STATUS
C0357	RM-90-150-00	MCI	N/A	Paracetamol Hydrochloride USP	04/01/08	E. Murphy	QC	New specification sheet sent report for new material	08/02/08	Johning CC form test
C0314	RM-3151	MCI	01	48 Paracetamol 10-15 MASH, NF	05/21/08	M. Patel	QC	Specification for lid seal corrected from redlin violet to violet. One particle size test specification for MASH 10 is corrected from 18.1 to 10.04 to meet USP 10.04 due to typographical error etc	08/06/08	J. Patel/Correction
C0370	N/A	N/A	N/A	Packaging components closure, ID # 7034, 7035, 7571, 7572, 7573, 7575 and 7573	06/19/08	D. Joffe	8K6	as a part of standardization of closures in packaging areas by replacing P122 liner and induction seal without liner to all closures as induction seal with liner. This is an improved seal for product protection	06/19/08	D. Joffe/Review
C0367	RM-300-02 RM-300-PRT-4J	MCI	00	Concarnalure Sodium, NF	08/06/08	J. Patel	QC	Current method with ID # 300, Rev # 06 is replaced by this eliminated reduce testing. Eliminated Q16 test, particle size updated to include the reference of method # RM-300-PRT-4J as per investigation # 03-005	08/06/08	J. Patel/Correction
C0377	MCI-20-059	MCI	01	Diflucan Tablets, USP	08/11/08	S. Patel	AB	Specifications for assay test updated as per USP monograph effective 08/01/08	08/21/08	J. Patel/Approval
C0493	N/A	Equipment	N/A	PTN 89-2000 Tablet Press ID # 00384	10/17/08	J. Jadhav	KPD	The software for the Picon Control Unit on the Picon 2000 tablet press was upgraded from version Picon T2.3 to Picon T2.4	10/28/08	E. Jadhav/Review
C0510	N/A	N/A	N/A	Paracetamol Tablets Analytical Balance, ID # 22N	10/27/08	S. Patel	40	Document major repair of the balance and perform	01/26/09	Re-approval

PLAINTIFFS' EXHIBITS 000135

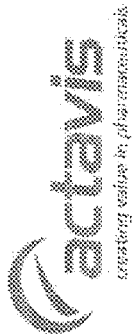


PMS
January 2008

Facilities PM's/Work Orders Preventive Maintenance Metrics

	Jul-08	Aug-08	Sep-08	Oct-08	Nov-08	Dec-08	Jan-09	YTD 2008
Work Orders Safety/Emergency/Hear Miss	N/AV	N/AV	0					0
Work Orders Safety/Emergency/Hear Miss Closed	N/AV	N/AV	0					0
Total PM's Actual (Closed)	N/AV	N/AV	218	183	161	206	148	916
Weekly PMs Backlogged > 1 day	N/AV	N/AV	0	0	0	0	0	0
Biweekly PMs Backlogged > 2 days	N/AV	N/AV	0	0	0	0	0	0
Monthly PMs Backlogged > 7 days	N/AV	N/AV	0	0	0	0	0	0
BiMonthly PMs Backlogged > 10 days	N/AV	N/AV	0	0	0	0	0	0
Qtrly PMs Backlogged > 14 days	N/AV	N/AV	0	0	0	0	0	0
Semi-Annual PMs Backlogged > 21 days	N/AV	N/AV	0	0	0	0	0	0
Annual PMs Backlogged > 30 days	N/AV	N/AV	0	0	0	0	0	0
Biennial PMs Backlogged > 30 days	N/AV	N/AV	0	0	0	0	0	0
PMs for the Month (Closed - %)	N/AV	N/AV	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Work Orders Requested	N/AV	N/AV	31	34	28	32	21	146
Work Orders Closed	N/AV	N/AV	31	34	28	32	21	146
Total PM/WO's Completed for Month	0	0	249	217	189	238	165	1058

Note:



Calibrations

January 2008

Facilities PM's/Calibrations

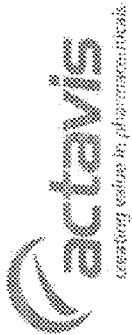
• Calibration Metrics

	Oct-08	Nov-08	Dec-08	Jan-09	
Total Due	64	99	191	65	
% Completed on time	98%	100%	100%	42%*	
Number past due (Month)	2	0	0	0	
New Calibrations Added ¹	19	39	25	30	
Total Active Cal Records	891	916	941	895	
Critical Out of Tolerances	2	3	1	1	

*Partial Month - work in progress

Added TP-0085 and TP-0086 PTK Presses (30 calibrations)

WT-AMW03 OOT, investigation initiated in Trackwise.



Action Items

- Manager and Director Training Syllabi need to be highlighted and for this reason they will be presented as a separate metric. This will be put down as an action.
- The number of expired SOP has fallen down to 7. These shall be closed by the 20th of January 2009.
- 51 overdue for closeout and a good percentage arise from investigations. All the open CAPAs for [REDACTED] and General GMP need to be addressed in a separate meeting.